



European Commission



Factsheet for Authorities in non-EU/EEA States on Medical Devices and *in vitro* Diagnostic Medical Devices¹

This Factsheet is aimed at regulatory/competent authorities in countries that are not part of the EU/EEA area. For a general overview of the impact of the Regulations please refer to the Medical Devices section on the DG GROW website.

The new Medical Devices Regulation (EU) 2017/745 (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) bring EU legislation into line with technical advances, changes in medical science, and progress in law making.

The new Regulations create a robust, transparent, and sustainable regulatory framework, recognised internationally, that improves clinical safety and creates fair market access for manufacturers.

In contrast to Directives, Regulations are directly applicable and do not need to be transposed into national law. The MDR and the IVDR will therefore reduce the risks of discrepancies in interpretation across the EU market.

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!



Introduction to the Medical Devices Regulation (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR)

The MDR will replace the existing Medical Devices Directive 93/42/EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). The MDR was published in May 2017, marking the start of a three-year period of transition from the MDD and the AIMDD.

The IVDR will replace the existing *In Vitro* Diagnostic Medical Devices Directive (98/79/EC) (IVDD). The IVDR was published in May 2017, marking the start of a five-year period of transition from the IVDD.

¹ The term 'devices' in this document refers to medical devices and *in vitro* diagnostic medical devices. For definitions of what is understood to be a device, see Article 2 of the MDR and the IVDR.

For medical devices (MDs) the transition period will end on **26 May 2020**, the “Date of Application” (DoA) of the MDR.

For *In Vitro* diagnostic devices (IVDs) the transition period will end on **26 May 2022**, the DoA of the IVDR.

During these two periods of transition, both Regulations will come into application gradually, starting with the provisions related to the designation of Notified Bodies and the ability of manufacturers to apply for new certificates under the Regulations.

To avoid market disruption and allow a smooth transition from the Directives to the Regulations, several transitional provisions are in place. Some devices with certificates issued under the Directives may continue to be placed on the market² until 27 May 2024 and made available³ until 27 May 2025.



Timeline

Until May 2025, products certified under the Directives and products certified under the Regulations will coexist on the market. Both will have equal status under the legislation, and no discrimination in public tenders may take place.

A transition period is needed as the new Regulations require the designation of Notified Bodies. In addition, manufacturers need to meet more stringent criteria, particularly in terms of clinical and performance evaluation requirements.

The designation process for Notified Bodies, which may take 18 months or more, involves assessors from both national and European authorities. This means that the first Notified Bodies designated under the new Regulations might be available by the beginning of 2019. You can find the Notified Bodies designated under the MDR and IVDR, as well as the scope of devices for which they are designated, on [NANDO](#)⁴. For more information refer to the contact points of the [competent authorities](#)⁵.

The rules for designating Notified Bodies are also more rigorous and add new requirements and responsibilities. The process of designating Notified Bodies will take up a significant part of the transition period, meaning that there will be limited time for manufacturers to get all their products certified before the respective DoAs.

This makes it unlikely that all devices available on the market will be certified under the new Regulations by the DoAs, especially if the designation of Notified Bodies takes longer than foreseen. To avoid market disruption and the unavailability of medical devices, manufacturers may under certain conditions continue to produce MDD/IVDD-compliant devices and place them on the market after the respective DoAs. After the DoAs and up to May 2025, you may therefore still receive MDD/IVDD-compliant products in your territory and be provided with certificates issued under the Directives.



What has changed?

In general, the MDR and the IVDR retain all the requirements of the Directives, , while adding some new requirements of their own. Compared to the current Directives, the new Regulations emphasise a life-cycle approach to safety, backed up by clinical data.

The Regulations add more stringent rules for the designation of Notified Bodies. For national competent authorities and the Commission, they add more control and monitoring requirements. The Regulations clarify the obligations of manufacturers, authorised representatives, importers and distributors.

The MDR reclassifies certain devices and has a wider scope than the Directives. For example, it explicitly covers devices for cleaning, sterilising or disinfecting other medical devices (MDR Article 2(1)). Similarly, the MDR covers reprocessed single-use medical devices (MDR Article 17) and certain devices with no intended medical purpose (MDR Annex XVI). The MDR also covers internet sales of medical devices and medical devices used for diagnostic or therapeutic services offered at a distance (MDR Article 6).

The MDR introduces a clinical evaluation consultation procedure for some Class IIb devices and for implantable Class III devices, to be carried out by an independent expert panel (MDR Article 54).

For IVDs, the biggest change concerns risk classification and the role of Notified Bodies. The IVDR classification rules assign each device to one of four risk categories, ranging from class A for lowest risk to class D for highest risk (IVDR Article 47). As a result, around 85% of all IVDs will need oversight from Notified Bodies, compared to 20% under the Directive. The IVDR also tightens the requirements for clinical evidence and conformity assessment.

A new Unique Device Identification (UDI) system (MDR/IVDR Article 27) greatly enhances the traceability and the effectiveness of post-market activities related to safety.

2 'Placing on the market' means the first making available of a device, other than an investigational device, on the EU market (MDR Article 2(28)).

3 'Making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge (MDR Article 2(27)).

4 <http://ec.europa.eu/growth/tools-databases/nando/>, NANDO (New Approach Notified and Designated Organisations)

5 http://ec.europa.eu/growth/sectors/medical-devices/contacts_en

The Regulations increase transparency, requiring the publication of information on devices and on clinical and performance studies related to their conformity. The new European Database for Medical Devices and *In Vitro* Diagnostic Medical Devices – EUDAMED – will play a central role in making data available and increasing both the quantity and quality of data (MDR Article 33 and IVDR Article 30).

CE marking

The assessment of the conformity of a device for CE marking (Conformité Européenne, or European Conformity) varies according to the risk class for both MDs and IVDs. Apart from the risk classification, certain features may influence the conformity assessment procedure, for example when an MD is required to be sterile or an IVD is designed for use by patients.

The assessment of the conformity of a device for CE marking (Conformité Européenne, or European Conformity) varies according to the risk class for both MDs and IVDs. Apart from the risk classification, certain features may influence the conformity assessment procedure, for example when an MD is required to be sterile or an IVD is designed for use by patients.

For MDs, all Class IIa, IIb and III devices as well as some specific Class I devices require the intervention of a Notified Body (MDR Article 52(7)(a⁶, b⁷, c⁸). MDR Article 52 and MDR Annexes IX, X and XI describe the different assessment routes according to the class of the device. In some cases manufacturers can choose their conformity assessment route from several options described in the Regulation.

There is a new clinical evaluation consultation procedure for Class III implantable devices and certain Class IIb devices, to be carried out by an independent expert panel. The Notified Body will have to take into consideration the scientific opinion expressed by the expert panel (MDR Article 54).

For IVDs, most Class A devices can be self-certified by their manufacturers unless they are sold sterile. Devices in Classes B, C and D will require conformity assessment by a Notified Body.

The conformity assessment of Class D devices will require the involvement of an EU Reference Laboratory designated for that type of device to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications (IVDR Article 48(5)). For innovative Class D devices where no Common Specifications exist, an independent expert panel must provide its views on the performance evaluation report of the manufacturer (IVDR Article 48(6)).

Availability of MDD/AIMDD/IVDD products vs MDR/IVDR products

During the transition period, products certified under the Directives and products certified under the Regulations will coexist on the market. Both will have equal status under the law provided that they are accompanied by appropriate certificates, and no discrimination in eligibility criteria in public tenders may take place.

Certificates issued under the Directives will remain valid, under certain conditions, until 27 May 2024 at the latest, although some obligations of the Regulations, like vigilance, post-market surveillance and registration of economic operators and devices will apply after the DoAs.

During the remaining validity of a certificate, a device can be covered by both a Directive and a Regulation certificate. Certificates of free sales may therefore be issued with the corresponding certificates under both the MDD and the MDR (for MDs) or both the IVDR and the IVDD (for IVDs).

Both types of certificate of free sales will be equally valid. Certificates of free sales that are based on valid certificates under the Directives will remain valid after 26 May 2020 (MDD) or 26 May 2022 (IVDD) and until the corresponding certificates expire.

Devices that are subject to certification by a Notified Body for the first time will have to be compliant by the Date of Application - 26 May 2020 for the MDR and 26 May 2022 for the IVDR. One example would be Class I medical devices that are sterile or have a measuring function.

Reclassification

MDD and IVDD certificates for products that are reclassified to a higher risk class under the MDR or the IVDR respectively remain valid until their expiration dates. The MDD/IVDD classification rules for these products will continue to apply until the expiration of the MDD/IVDD certificates⁹.

MDD/IVDD products in the supply chain

MDs and IVDs that were placed on the market after 26 May 2020 (for MDs) or after 26 May 2022 (for IVDs) by virtue of a valid certificate issued before that date may be made available until 26 May 2025. After 27 May 2025, any of these devices that have not reached the final user will have to be removed from the supply chain.

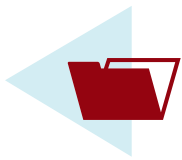
Devices that have been placed on the market and put into service, so that they have reached the final end user before 26 May 2025, can continue to be used by the user. The Regulations do not cover second-hand products (MDR/IVDR Recital 3).

6 "Devices placed on the market in sterile condition, to the aspects relating to establishing, securing and maintaining sterile conditions".

7 "Devices with a measuring function, to the aspects relating to the conformity of the devices with the metrological requirements".

8 "Reusable surgical instruments, to the aspects relating to the reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use".

9 <https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/>



What does this mean?

'Making available on the market' means any supply of a device, other than an investigational device, for distribution, consumption or use on the EU market, whether in return for payment or free of charge (MDR Article 2 definition 27, IVDR Article 2 definition 20).

'Placing on the market' means the first making available of a device, other than an investigational device, on the EU market (MDR Article 2 definition 28, IVDR Article 2 definition 21).

'Putting into service' means the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use for its intended purpose on the EU market for the first time (MDR Article 2 definition 29, IVDR Article 2 definition 22).



Responsibilities of economic operators

The Regulations clearly define the obligations of the various actors and their relations.

MDR/IVDR Article 10 describes the obligations of **manufacturers**, for example regarding risk management systems (paragraph 2) and quality management systems (paragraph 9). The article also specifies the need to conduct clinical evaluations or performance studies (paragraph 3), draw up technical documentation (paragraph 4), and undertake conformity assessment procedures (paragraph 6). The Regulations make manufacturers responsible for their devices once they are on the market (paragraphs 12, 13 and 14). Manufacturers must have systems in place to cover their financial responsibility for harm caused by defective devices (paragraph 16).

Every manufacturer shall have a named person responsible for regulatory compliance (MDR/IVDR Article 15).

Manufacturers outside the EU/EEA must have an **authorised representative** whose place of business is in one of the EU/EEA Member States.

The Regulations set out the list of tasks that shall be delegated to authorised representatives (MDR/IVDR Article 11). At a minimum, authorised representatives' obligations include verifying that the EU declaration of conformity and the technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer. An authorised representative must also keep copies available of certain documents and cooperate with authorities on request. The authorised representative is legally liable for defective devices jointly and severally with the manufacturer.

A change of the authorised representative requires a proper agreement that defines the arrangements between the manufacturer and both the outgoing and the new authorised representative (MDR/IVDR Article 12).

The Regulations describe the roles and responsibilities of **importers** (MDR/IVDR Article 13) and **distributors** (MDR/IVDR Article 14):

- 1. Importers** are responsible for ensuring that the devices they place on the market comply with the Regulations and are registered in EUDAMED, and that the manufacturer has fulfilled its obligations. They also have the responsibility to inform manufacturers and authorised representatives in the event of complaints or reports of suspected incidents from healthcare professionals, patients or users.
- 2. Distributors** should ensure, by representative sampling, that the devices they distribute comply with the Regulations. They also have the responsibility to inform manufacturers or authorised representatives and importers of complaints and incidents.

Economic operators must record the UDIs of the devices they supply or are supplied with in accordance with MDR Article 27(8) and IVDR Article 24(8).



More stringent clinical evaluation requirements

The new Regulations reinforce the requirements for clinical/performance evaluation (MDR/IVDR Chapter VI). These introduce some of the biggest changes compared to the previous regime.

As under the Directives, clinical/performance evaluation involves collecting clinical data already available in the literature as well as setting up any necessary clinical investigations (MDs) or performance studies (IVDs).

For medical devices, the concept of equivalence with other devices for which clinical data already exists can be used in a limited number of situations, but the new rules are tighter (MDR Article 61(4, 5, 6)).

The MDR introduces a clinical evaluation consultation procedure by an independent expert panel for some Class IIb devices and for implantable Class III devices (MDR Article 54).

The conformity assessment of class D IVDs will require the involvement of an EU Reference Laboratory, if designated for that type of device, to verify the performance claimed by the manufacturer and compliance with the applicable Common Specifications (IVDR Article 48(5)). In addition, for innovative class D devices where no Common Specifications currently exist, an independent expert panel must provide its views on the performance evaluation report of the manufacturer (IVDR Article 48(6)).

Safety and clinical performance

Easily understood summaries of safety and clinical performance will be made publicly available for implantable and Class III MDs (MDR Article 32) and for IVDs in Classes C and D (IVDR Article 29). These summaries will form part of the technical documentation of the manufacturer and will be available via EUDAMED.



Reinforced post-market surveillance

The new Regulations strengthen the post-market surveillance requirements for manufacturers. They also reinforce cooperation between EU Member States in market surveillance:

1. Periodic safety update reports

Periodic safety update reports will have to be prepared for all MDs (MDR Article 86) and IVDs (IVDR Article 81), except MDs in Class I and IVDs in Classes A and B. These reports summarise the analysis of post market surveillance data. The frequency of the updates will depend on the classification of the device. The updates shall be submitted to the Notified Bodies and competent authorities.

2. Trend reporting

The Regulations also require trend reporting for all devices. Trend reports record any increase in the frequency or severity of non-serious incidents or expected undesirable effects, particularly when they may affect the risk assessment of the device (MDR Article 88 and IVDR Article 83).



Supply chain traceability and Unique Device Identifiers (UDIs)

A completely new feature of the Regulations is the system of Unique Device Identifiers (UDIs) (MDR Article 27 and IVDR Article 24). This will enhance the identification and traceability of devices.

The manufacturer is responsible for affixing the UDIs and filling in the requested information in the UDI database that is part of EUDAMED. In most cases the UDI will be available in human-readable form and also for example as a barcode.

Each MD or IVD and, as applicable, each package will have a UDI composed of two parts. The first part is a device identifier (UDI-DI) specific to a manufacturer and a device. The second part is a production identifier (UDI-PI) – such as a lot number or a serial number – to identify the unit of device production and, if applicable, the package. Every level of packaging will be uniquely identified.

For both Regulations, the deadline for assigning UDIs is the respective DoA. However, the obligation to affix the UDI on the labelling will be implemented in three stages. For MDs, the UDI should be affixed at the latest by:

1. Class III devices: 26 May 2021
2. Class II devices: 26 May 2023
3. Class I devices: 26 May 2025

and for IVDs:

1. Class D devices: 26 May 2023
2. Class B and Class C devices: 26 May 2025
3. Class A devices: 26 May 2027

Before these dates there is no legal requirement for manufacturers to label their devices with UDIs, although some manufacturers may choose to do so.

For reusable devices there will be a requirement to affix UDI direct marking on the device itself. The timeline for affixing UDI direct marking is also staged, and comes into effect a further two years after the date applicable to the corresponding risk class, as shown in the two lists above.



Transparency

The new EUDAMED database will include information on UDIs, registration of economic operators (except for distributors) and devices, certificates, clinical and performance investigations, post-market surveillance, vigilance and market surveillance (MDR Article 33 and IVDR Article 30).

Regulatory authorities will be able to check whether a manufacturer is registered in EUDAMED, and access basic information on devices. They can also verify that the devices are covered by an appropriate certificate.

The information in EUDAMED will be uploaded by, and accessible to, all (including the general public) at levels depending on their access rights and the information they are responsible for uploading. The database will facilitate access to the regulatory documentation through the UDI, providing access to the certificates covering the devices.

EUDAMED will also be used by manufacturers to report incidents and as a platform for EU/EEA authorities to cooperate and exchange information.

For competent authorities in countries outside the EU/EEA

As an authority in third countries that **export** devices to the EU, you may receive requests for information from manufacturers in your country wishing to place devices on the EU market. You should make your manufacturers, national associations and chambers of commerce aware of the new rules, timelines and obligations under the new Regulations. Refer them to the website of the European Commission or the authorities' contact points for further information on the application of the Regulations or for guidance.

As an authority in third countries that **import** devices from the EU, you need to be informed about the timelines for implementing the Regulations and to bear in mind that MDD- or IVDD-compliant products are likely to be on your markets after the DoA of the Regulations. To avoid disruptions on your market you should inform your health institutions, procurement bodies, customs officers and importers about the new requirements and the applicable timelines, and clarify the various transition provisions regarding, for example, the reclassification of products to higher risk classes or labelling requirements.

- for the continued marketing of devices that comply with the Directives (see below); and
- to serve as a backup in case EUDAMED is not fully functional by the DoA.

What is the applicable legislation up to the respective DoA?

Until the DoA, the laws and regulations adopted by Member States in accordance with the Directives will continue to apply. However, there are some exceptions.

Is it possible to place devices on the market that are compliant with the Regulations prior to the DoA?

Yes, manufacturers may place compliant devices on the market before the end of the transitional period. This applies to devices in all risk classes, and includes for example custom-made devices, systems and procedure packs.

Medical devices that are subject to the clinical evaluation consultation procedure according to MDR Article 54, and IVD Class D devices according to IVDR Article 48(6), may not be placed on the market before the expert panels have been established.

Depending on the risk class of the device, conformity assessment may involve an appropriate Notified Body. This requirement may create further delays before such devices can be placed on the market.

Which obligations of the Regulations do manufacturers need to fulfil in order to place compliant devices on the market before the DoA?

Manufacturers should meet as many obligations as possible, bearing in mind that the complete MDR/IVDR infrastructure, including EUDAMED, may not be fully functional before the respective DoA.

Both the device and the manufacturer must comply with the Regulations. Manufacturers should undertake an assessment of the conformity of their device.

Do certificates issued by Notified Bodies under the existing Directives remain valid after the DoA?

Yes, certificates will generally remain valid until the end of the period indicated on the certificate, or until 27 May 2024, whichever is the earlier. After 27 May 2024 certificates issued under the Directives will become void.



Frequently asked questions

For a complete list, see the list of FAQs from the Competent Authorities for Medical Devices at:

<https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/>

When do the Regulations apply?

The Medical Devices Regulation (MDR) (2017/745/EU) will apply from 26 May 2020 and the *In Vitro* Medical Device Regulation (IVDR) (2017/746/EU) will apply from 26 May 2022 – the respective Dates of Application (DoAs).

Some provisions of these Regulations will apply earlier (e.g. regarding Notified Bodies and the Medical Device Coordination Group). Some will apply later (e.g. Unique Device Identification and labelling).

When do the existing Directives cease to apply?

In general, Directives 90/385/EEC and 93/42/EEC will be repealed with effect from 26 May 2020 and Directive 98/79/EEC will be repealed with effect from 26 May 2022. However, there are some exceptions, such as:

Can manufacturers still place on the market/put into service Directive-compliant devices after the end of the transition period?

Yes, under certain conditions there will be an option to continue placing on the market/putting into service devices that comply with the Directives until their existing certificates expire. This may avoid the immediate need for a new certificate under the Regulations.

To use this option, all the existing certificates will have to be valid (including, for example, the QMS), the purpose and nature of the device must not change, and manufacturers must apply the new requirements with regard to registration, surveillance and vigilance.

What is the “sell-off” provision about?

The “sell-off” provision is intended to limit the time during which devices that are compliant with the Directives and have already been placed on the market may be made available.

Any devices that are still within the supply chain and that have not reached their final user as being ready for use, for example a hospital, on 27 May 2025 are no longer marketable and must be withdrawn.

Once a Directive-compliant device has been made available to the final user by the deadline, the further making available of this device is not subject to the Regulations.

20/11/2018

© European Union, [2018] Reuse is authorised provided the source is acknowledged.
The reuse policy of European Commission documents is regulated by Decision 2011/833/EU (OJ L 330, 14.12.2011, p. 39).

Funded under the Third EU Health Programme

ISBN: 978-92-79-90405-9 DOI: 10.2873/850249



https://ec.europa.eu/growth/sectors/medical-devices_en